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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,220	03/17/2004	Masaki Sunami	227833	3562

23460 7590 01/05/2010

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EXAMINER	
PAGONAKIS, ANNA	

ART UNIT	PAPER NUMBER
1628	

NOTIFICATION DATE	DELIVERY MODE
01/05/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/802,220	SUNAMI ET AL.	
	Examiner	Art Unit	
	ANNA PAGONAKIS	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 15-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 15-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In view of the Appeal Brief filed on June 15, 2009, **PROSECUTION IS HEREBY REOPENED**. New grounds of rejection are set forth below.

To avoid abandonment of the application, Appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then Appellant must pay the difference between the increased fees and the amount previously paid.

Claims 1-8 and 15-23 are pending and under examination.

Applicant's arguments, presented in the Appeal Brief filed June 15, 2009, have been fully considered and are persuasive regarding the application of Englert et al. (U.S. 6,723,751) as prior art. Accordingly, the rejections as set forth against claims 1-8 and 15-23 over the reference has been withdrawn. Rejections not reiterated from the final Office Action are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Priority

This application claims benefit of 60/455,293 filed 3/17/2003; 60/460,521 filed 4/4/2003; 60/477,202 filed 6/10/2003 and 60/493,649 filed 8/8/2003.

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, 60/455,293 filed 3/17/2003; 60/460,521 filed 4/4/2003; 60/477,202 filed 6/10/2003, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. All claims are not adequately supported or enabled by the prior-filed applications the subject matter in claims 2-5 and 18-23. It is noted that Applicant is not entitled to the priority date in these application for all claims in the instant claim set because the information contained within the previous referred filings does not support the granting of an earlier filing date. There is no instance, throughout the specification, of any calculation of any ratio. **Claims 2-5 and 18-23 are given a priority date of October 4, 2006.**

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 5, is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not reasonably be appraised of the scope of the invention. The term is unclear because meets and bound of "substantially" is not clear. For instance, is

the cholesteryl ester transfer protein inhibitor 99.9 percent crystalline or 51 percent crystalline. For purposes of prosecution, the term "substantially" is interpreted as greater or equal to 50 percent crystalline.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Gumkowski et al. (U.S. 2003/0022944 A1) and Ault et al. (U.S. 7,049,283) in view of Huang et al. (Clinical Science, 2002, 103, 587-594; already of record) and Cayman Chemical Company (JTT-705, 8/18/2009).

Gumkowski et al. teach that CETP inhibitors are generally hydrophobic and thus have extremely low solubility and thus have low oral bioavailability [0002]. Various attempts have been made to improve the aqueous concentration of CETP inhibitors, but generally have met with limited success (paragraph [0010]).

Gumkowski et al. is silent on the administration of crospovidone.

Ault et al. teaches a composition suitable for oral delivery of pharmaceutically active agents, comprising a therapeutically effective amount of a pharmacologically active agent; a crospovidone or povidone; and a delivery agent for said pharmacologically active agents (abstract). Furthermore, the reference teaches the composition containing crospovidone versus the comparative compositions which do not contain crospovidone, resulting the greatly enhanced oral bioavailability of the formulations (column 9, lines 34-38).

Ault et al. is silent on the use of a CETP inhibitor as JTT-705.

Huang et al. teaches that JTT-705 is a well known CETP inhibitor (abstract).

Cayman Chemical teaches that JTT-705 is a crystalline solid (page 2).

It would have been obvious to one of ordinary skill in the art to formulate a composition comprising a CETP inhibitor, such as JTT-705, and crospovidone because crospovidone is known to enhance the oral bioavailability of pharmacological agents as taught by Ault et al. and CETP inhibitors are known to have low oral bioavailability, per Gumkowski et al..

With respect to claim 7, the ratio of the CETP inhibitor, JTT-705, and crospovidone is within the skill of the artisan at the time of the invention and would not have required undue experimentation or have been outside the realm of knowledge generally available to the skilled artisan. Factors that would have been taken into consideration when making such a determination would have included, but not have been limited to, the age, weight, sex, diet and medical condition of the patient, severity of the disease, route of administration, pharmacological considerations, e.g., activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered as part of a drug combination. Thus, the ratio that would have actually been employed would have been expected to vary widely and, in the absence of evidence to the contrary, would not have been inconsistent with that which is presently claimed.

Claims 15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gumkowski et al. (U.S. 2003/0022944 A1) and Ault et al. (U.S. 7,049,283) in view of Huang et al. (Clinical Science, 2002, 103, 587-594; already of record) and VascularWeb (2009).

Gumkowski et al. teach that CETP inhibitors are generally hydrophobic and thus have extremely low solubility and thus have low oral bioavailability [0002]. Various attempts have been made to improve the aqueous concentration of CETP inhibitors, but generally have met with limited success (paragraph [0010]). The presence of CETP inhibitors in the blood function to increase HDL cholesterol and lower LDL cholesterol levels (paragraph [0008]).

Gumkowski et al. is silent on the administration of crospovidone.

Ault et al. teaches a composition suitable for oral delivery of pharmaceutically active agents, comprising a therapeutically effective amount of a pharmacologically active agent; a crospovidone or povidone; and a delivery agent for said pharmacologically active agents (abstract). Furthermore, the reference teaches the composition containing crospovidone versus the comparative compositions which do not contain crospovidone, which results in enhanced oral bioavailability. (column 9, lines 34-38).

Ault et al. is silent on the use of a CETP inhibitor as JTT-705.

Huang et al. teaches that JTT-705 is a well known CETP inhibitor (abstract).

Vascular Web teaches that the treatment of hyperlipidemia involves the lower of LDL cholesterol (under How is hyperlipidemia treated?).

One of ordinary skill in the art would have been motivated to administer a CETP inhibitor, such as JTT-705, for the treatment of hyperlipidemia because CETP inhibitors, such as JTT-705, are known to decrease LDL cholesterol which is necessary in order to treat hyperlipidemia. Further, one would have been motivated to administer crospovidone in combination with JTT-705 in order to ensure oral bioavailability of the pharmacological agent. one of ordinary skill in the art would have a reasonable

expectation of success because crospovidone is well known in the art to enhance oral bioavailability of pharmacological agents.

With respect to claims 18-23, it is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642